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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,457	03/12/97	CARDY	D 960670.ORI

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EXAMINER	
EWOLDT, G	
ART UNIT	**PAPER NUMBER**
1644	22

DATE MAILED: 01/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/737,457	Cardy et al.
Examiner	**Group Art Unit**
Gerald Ewoldt	1644

☒ Responsive to communication(s) filed on *Sep 18, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-3, 5-12, and 14-24* is/are pending in the application.

Of the above, claim(s) *24* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 5-12, and 14-23* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-3, 5-12, and 14-23 are being acted upon.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. As noted in the previous action, the peptide sequences on page 11, line 5, page 12, line 1, and page 13, line 10 of the specification must be brought into sequence compliance. **It is noted that Applicant has failed to respond to this requirement as set forth in the previous two actions.**

3. In view of Applicant's response, filed 9/18/00, only the following rejections remain.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-11, and 20-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,283,323 (of record), for the reasons set forth in Paper No. 19, mailed 6/13/00.

Applicant's arguments, filed 9/18/00, have been fully considered but have not been found convincing. Applicant again argues (as in Paper No. 18, filed 4/3/00) that the '323 patent does not teach a translocation portion. However, a translocation portion is inherent to the immunoglobulin (Ig) of the prior art. Applicant further argues unclaimed limitations including an "active" translocation portion and the "governance" of the fate of BCR complexes. Unclaimed limitations need not be considered. Applicant further argues that the DeFranco (1999) reference cannot be considered prior art. Said reference was used only as evidence of the enablement of the polypeptide of the prior art and not as prior art itself.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 5-12 and 14-23 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in Paper No. 19, mailed 6/13/00.

8. Applicant's arguments, filed 9/18/00, have been fully considered but have not been found convincing. Applicant again argues (as in Paper No. 18, filed 4/3/00) that the references cited by the Examiner are inapposite because they relate to limitations seen with certain cell lines and immune assays where *in vitro* effects are not always the same as those seen *in vivo*. Applicant further argues that in their case their *in vitro* assays "precisely mimic the mechanisms occurring *in vivo*." Applicant also argues that MHC presentation is required for an *in vivo* effect. While MHC presentation is required and necessary for immune activation, it is not sufficient. MHC presentation is but one component of a multi-step process leading to an immune response. Applicant further fails to explain why the disclosed T-cell and APC clones used in the disclosed assays provide sufficient guidance in the face of cited references to the contrary. It is again noted that one of the cell lines used in the disclosed assays (Sp2/0) is an "ageless" cell line of unknown origin such as is discussed by Dermer (1994, of record). Finally, Applicant fails to provide guidance as to how the same invention used in the same method of immunomodulation can provide a treatment for conditions requiring both immunostimulation and immunosuppression. Applicant offers no new evidence in support of enablement and essentially the same arguments as offered in Paper No. 18, filed 4/3/00. Applicant is reminded that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP § 2145.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 5-12, and 14-23, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Casten et al. (1988, of record) in view of Fawell et al. (1994, of record), and Noguchi et al. (1994, of record), for the reasons set forth in Paper No. 19, mailed 6/13/00.

Applicant argues a lack of motivation to combine the references and that Casten et al. actually teaches away from the claimed invention in that Casten et al. does not teach "active" internalization and that internalization and processing are not required in all cases. However, as previously stated, "active" internalization is an unclaimed (as well as undefined) limitation. Further, whether internalization and processing are required in all cases or not, internalization is taught by the reference and processing is a property of said internalization. Also, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant further argues that Fawell et al. teaches away from the instant invention in that the reference teaches the use of the HIV Tat protein for the cellular delivery of cargo and not for specific cell binding. However, the Casten et al. reference teaches specific binding while the Fawell et al. reference teaches that the HIV Tat protein confers cellular translocation on four disparate proteins and further teaches the advantages of the use of HIV Tat for the general delivery of proteins into cells, thus providing motivation for its use as a translocation component in the instant invention. Noguchi et al. teaches that p53 is an "obvious candidate" for tumor recognition because of its widespread expression on tumors, thus providing motivation

for its use as an effector component in the instant invention. In combination, the references serve to demonstrate the motivation to produce the claimed invention.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 22, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600